

Seeking Consistent Excellence in Patient Care....and in Life

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“Patient safety” is a great buzz-phrase thrown around freely in a variety of situations. Real progress in patient safety, however, requires more than lip service. Improving patient safety is not only the right thing to do from a moral and ethical perspective, it is the smart thing to do from a business perspective. As consumers and others become better informed as to what constitutes safe care, they will accept nothing less—and will severely penalize those who fail to provide it.

Human Factors and Ergonomics

Hazard and harm to patients, as well as inefficiencies in health care, have been described as worldwide problems that result in hundreds of thousands of patient deaths and billions of dollars in waste every year.

If real, sustainable progress in safe and efficient health care delivery is to be achieved, an engineering-based approach, heavily rooted in **Human Factors and Ergonomics (HFE)** must play a foundational role.

HFE considers the application of what we know about people, their abilities, characteristics and limitations (or opportunities for error) to the design of the equipment they use, jobs they perform and environments in which they function. One common cause of the lack of widespread success in patient safety activities may stem from a continuing failure to identify the underlying systems-based causes for patient safety problems.

In other words, how humans can accidentally cause harm even when abiding by safety rules or using equipment as it was designed.

Without the consideration for HFE in the evaluation of an error, the search for causation often ends with superficial descriptions of causation that are not systems-based and typically only ascribe “human error” as the culprit, without examining the underlying causes for those human errors. This is akin to blaming your teenager for leaving the garage door open when he left the house, when in reality, there was a system error that caused the door to re-open after he pushed the button to close the door. True, he didn’t check to see that the door had closed completely before riding off into the sunset, but he did do his part in activating the automatic closer to begin with. HFE comes into effect in the fact that he did not ensure the door closed and stayed closed before riding away on his bike. We all have habits of blaming first and then finding out what really happened later. The HFE approach takes the blame out of the situation, asking investigators to not only discover how and why the error happened, but also what systems can be put into place that would prevent this error from happening again in the future.

The response of treating the symptoms instead of the underlying causes is not exclusive to health care, but rather a characteristic demonstrated when organizations and individuals are confronted with mishaps.

A systems-based approach

As is often the case with most adverse life events, inadequate communication is cited as the single largest cause of patient safety failures. To combat miscommunication in health care or other professional settings, consistent written and verbal communications must take place. This is especially true in hierarchical situations where guidance may unknowingly be needed. When rules, regulations and expectations are clearly understood and consistently verbalized, mistakes happen less often, things run more smoothly and satisfaction is greater.

Awareness and implementation of HFE can positively impact the delivery of health care from a safety, efficacy and efficiency perspective. Improvement opportunities run the gamut, from equipment and physical plant design to process issues that address organizational and personal factors. **In some cases, re-engineering existing facilities, equipment and processes can result in the development and implementation of new tools and approaches to obtain sustainable, successful patient-safety results.**

Once the concept of HFE is understood, its system-based approach can be employed to improve processes and design throughout many areas of life.

Delivering Quality Care Consistently

Consistent patient safety only happens as the result of deliberate intention. Developing a system that allows for consistent process improvement that considers every newly discovered vulnerability is the only way to consistently prevent harm to patients and others.

Such a system requires this HFE approach to root-cause analysis that moves beyond superficial and inadequate questions such as, “Whose fault is this?” to the more meaningful and productive questions such as, “What happened?” “Why did it happen?” and “What do we do to prevent it from happening in the future?”

So, to truly improve patient safety, the overall **goal** must be **to prevent harm to the patient; not to eliminate errors**. This is no different than looking into making improvements in any area of life. If your goals are to ‘avoid making mistakes’ you miss the opportunity for a more inspirational goal that provides a greater return than simply avoiding error. In the example of the teen, the goal should be “to protect the home,” not to simply shut the garage door. From the perspective of protecting the

Developing a Patient Safety Program

Step 1: Establish a goal that people will rally around, such as “preventing harm to the patient.”

Ensure everyone understands the **goal** as “**to prevent harm;**” **not simply to eliminate errors.**

Step 2: Create a discovery and reporting system perceived as fair and transparent. Prioritize and establish how resources will be applied toward patient safety efforts.

Step 3: Provide tools that support root-cause analysis. Move beyond blame and develop your system so that action results in improvement, not only analysis. All activities must be evaluated against this requirement.

Step 4: A formal evaluation to assess the success of the intervention must be a part of all improvement systems to achieve the desired outcome.

This evaluation also ascertains that no unintended negative outcomes were associated with the intervention.

A multipronged approach that takes into account “systems thinking” can ensure that errors do not result in patient harm. In other words, **how can we implement systems that will actually prevent humans from being able to cause inadvertent harm?**

home, the teen might take extra care to not only do as he's told, e.g. shut the garage door, but also to ensure that the garage door finished closing and remained shut in a manner that someone else cannot get into the house without breaking in, thus protecting the house from easy unwelcomed entry. One might guess that this would be understood, but without specific clarification of the overarching goal, "humanness" factors in, which could be as simple as, "I was in a hurry. I did what I was supposed to do. I followed the rules... but the system failed" (in the case of the garage door, faulty wiring or a garage door system failure or simply something in the way of the sensors).

Along with poor communication, another great contributor to harm is simply the lack of acceptance that a problem even exists (aka: a varying degrees of ignorance and arrogance).

It is vital to create an environment of acceptance by the entire organization and communicate relentlessly—both in word and in deed—that patient safety is the foundation on which quality health care is built. **If the patient is not safe from medically induced harm, then high-quality care cannot exist.**

Adverse events related to surgery continue to occur worldwide despite the best efforts of clinicians. **Teamwork and effective communication are known determinates of surgical safety. By identifying "Prevention of harm" as the goal, leadership clearly communicates what is to be achieved and maximizes the probability of success.** Care teams can then approach every situation from the perspective, "is this good for the patient / the right thing to do in this situation," rather than "am I following the rules properly?"

Choosing "to prevent harm to patients under our care" as the ultimate goal is easy for everyone to rally around. While clinicians believe safety is important, it is not always operationally important to everyone to fix processes, because they either believe that that is someone else's job, and they believe that they, their floor, their practice and their institution already are safe and already do practice safety measures.

- If you do not believe a problem exists, you cannot fix it.
- If you know a problem exists and you don't feel empowered to fix it, you won't.
- If you know that it is your responsibility to spot potential vulnerabilities and hazards and you know you are empowered to address them, you might.
- **When you're fully committed to the goal, you will be in the optimal position to make a difference.**

Elimination of errors vs. Prevention of harm

When discussions turn to the elimination of errors, many view this effort as something others must do, not something that they must do. Even the use of the term "error" is misguided because the determination as to whether a given act was an error is subjective. It is the product of a retrospective assessment and it detracts from focus of the real goal, which is to avoid causing patient harm. Instead of helping, this determinant can become a punitive fault-finding witch-hunt, which does little to either arrive at the true underlying causes or create robust solutions. As long as

most individuals believe that the problem is someone else's, they have little motivation to change what they themselves are doing. This means that everyone is waiting for everyone else to fix something, and therefore nothing or little of importance is fixed.

In organizations where an effective safety program and culture exists, everyone accepts that safety is each person's responsibility and that no one is immune to involvement in a problem. Individuals who believe that safety is not an issue are viewed as the most dangerous person in the room, because not only are they not looking for opportunities to mitigate errors, they assume errors will not take place, which is the opposite of continually seeking to prevent patient harm.

Getting people to fully embrace the goal of preventing harm is relatively easy, but getting them to accept that it is *their personal responsibility* is tougher. The perception of fairness is the real litmus test because people tend to act and react based on whether they believe they are being treated fairly, not on what someone tells them is fair or is codified in a policy or regulation. **Thus, the need to define exactly what constitutes a blameworthy act is crucial to this idea of fairness.**

Blameworthy

Defining which types of events can result in punitive action (blameworthy) is critical to the overall success of a patient safety program. The definition has to be readily comprehensible— not dependent on legal mumbo jumbo—and have validity with all parties, from health care workers and administrators to regulators and patients. Each party has to believe that the definitions and resulting actions will be fair. This overriding requirement to be perceived as fair is critical because if individuals do not have confidence that they and their colleagues will be treated fairly, they will not trust the patient safety system and therefore will not fully support it.

A blameworthy occurrence can be described as “An intentionally unsafe act,” defined as any of the following: 1. a criminal act, 2. an act involving alcohol or substance abuse on the part of the care provider, or 3. a purposely unsafe act. The term “purposely unsafe act” could be further defined as an act recognized by the individual as being unsafe, yet was committed anyway, with no mitigating reasons. This definition clarifies that an occurrence, such as a rule violation, in and of itself is not necessarily an intentionally unsafe act because by itself it does not necessarily affect safety in a harmful manner, and in fact, may be the safest way to proceed in caring for a patient in a particular circumstance.

Learning and Accountability

To function effectively in the area of patient safety, all organizations need to have both learning and accountability functions. Learning systems should take a systems-based approach, focusing on what happened, why it happened and what is needed to prevent it from happening in the future. It should be carried out in a way that is viewed as fair and non-punitive and should not focus on who is to blame.

Accountability systems, on the other hand, focus on the individual: who made a mistake, what should happen in the future to correct this individual's flawed performance, and consequences to the individual for this failure.

Both systems are necessary and should not be merged, less they lose their utility and integrity. Once merged, they become viewed wholly as an accountability system, placing blame rather than discovery, often because people find themselves at the mercy of their supervisors with nothing more to rely on than the goodwill of the supervisor. Without this parallel structure, the learning system will be defunct.

Identifying Vulnerabilities

Reporting systems are great tools to use when identifying vulnerabilities within your organization / system. You cannot begin to correct a problem or vulnerability until you know that it exists.

As far as patient safety is concerned, the reporting system should be looked at as a vulnerability detector, not as a measurement of incidence or prevalence.

Many organizations view the data in reporting systems as a true reflection of what is really happening in their organization. It is important to note that this is in no way a reliable assumption. Reports have numerous sources of bias. They are good for measurement of many things, but as far as patient safety is concerned, the reporting system should be looked upon as a vulnerability detector, not as a sure measurement of incidence or prevalence. Once a vulnerability is identified, it is up to the organization to determine if and what type of action should be taken, ideally using an explicit, transparent and risk-based methodology.

To detect vulnerabilities, organizations should not restrict themselves to only those events that actually resulted in harm to the patient (or the organization). Well-run safety systems have embraced the notion that **close calls are an outstanding way to identify vulnerabilities** and mitigate the associated risks without harm to a patient. Even though this approach makes sense, few organizations actively solicit or collect close call reports, and fewer still methodically investigate or analyze those reports to determine corrective actions. "High Reliability" organizations view close calls as the cornerstone of a robust safety program. **Organizations that don't measure close calls are still at a primitive level of safety related sophistication.**

An organization whose policy does not include close call reporting and associated actions is essentially saying that it does not care to learn until a patient is injured. To paraphrase an old aphorism, experience is the best teacher, but is also the most expensive teacher. In the case of health care, those who don't measure close calls force the patient to pay their tuition in the form of pain and suffering.

Taking Corrective Action

Simply receiving reports without investigating, analyzing and acting is doing nothing to prevent harm to the patient. Once leadership is aware of and receives reports on patient harm and close calls, a prioritization system that employs explicit, unbiased, risk-based and publicly reviewable criteria is needed to rationally determine which reports warrant further analysis and action.

Culture does not change solely by issuing policies and directives. Once an action plan is defined, it is necessary to ensure that correct actions are taken by each member of the team, that the actions produce desired improvements, and that unintended negative consequences do not occur.

To create and maintain excellence in patient safety, everyone must play an active role. It is everyone's job to continuously look for better ways to reduce the occurrence of opportunities that might cause patient harm. With everyone's eyes, ears and commitment, excellence in patient care can prevail consistently.

Safety is a never ending marathon. Strong, unwavering leadership is required: leadership that sets the tone, provides the tools, and creates the environment for open communication, and action, to improve patient safety. With this sort of leadership, cultural change is a process of continuous discovery, awareness and improvement. It cannot be accomplished overnight; yet, the results are worth the effort and our patients deserve nothing less.

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Dr. James Bagian is a physician, engineer and astronaut who currently serves as a professor in the Department of Anesthesiology and as the Director of the Center for Healthcare Engineering and Patient Safety at the University of Michigan where he focuses on creating solutions that will make health care safer, more effective and more efficient for patients. Previously, Dr. Bagian served as the first Chief Patient Safety Officer and Founding Director of the National Center for Patient Safety (NCPS) at the U.S. Department of Veterans Affairs (VA). He has also held positions as a NASA physician and astronaut, U.S. Air Force flight surgeon, and engineer at the U.S. Department of Housing and Urban Development, U.S. Navy, and Environmental Protection Agency.

During his 15-year tenure with NASA, Dr. Bagian flew on two Space Shuttle missions. He led the development of a high-altitude pressure suit for crew escape as well as other crew survival equipment. He was the first physician to successfully treat space motion sickness and his approach has been the standard of care for astronauts ever since. He also served as an investigator in the inquiry following the 1986 Challenger accident and was appointed as Medical Consultant and Chief Flight Surgeon for the Columbia Accident Investigation Board (CAIB).